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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,583	07/11/2002	Joyce S. Plested	11560-003US1	2536
49443	7590	03/09/2006	EXAMINER	
PEARL COHEN ZEDEK, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Interview Summary	Application No.		Applicant(s)	
	10/089,583		PLESTED ET AL.	
	Examiner		Art Unit	
	S. Devi, Ph.D.		1645	

All participants (applicant, applicant's representative, PTO personnel):

(1) S. Devi, Ph.D. (3) _____

(2) Marc Tritel for Mark Cohen. (4) _____

Date of Interview: 28 February 2006.

Type: a) ☒ Telephonic b) ☐ Video Conference
c) ☐ Personal [copy given to: 1) ☐ applicant 2) ☐ applicant's representative]

Exhibit shown or demonstration conducted: d) ☒ Yes e) ☐ No.
If Yes, brief description: Proposed after-final amendment and response.

Claim(s) discussed: All of record, independent claims in particular.

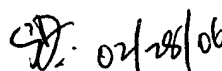
Identification of prior art discussed: Plested et al. 1999.

Agreement with respect to the claims f) ☐ was reached. g) ☒ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: See Continuation Sheet.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.


S. DEVI, PH.D.
PRIMARY EXAMINER

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments:

Mr. Tritel asked whether the proposed claims and the response (enclosed) addresses the enablement issue. He was reminded that the pending 35 USC, 112 first paragraph rejection is a new matter rejection, and not a lack of enablement rejection. How Applicants did not have possession of different antibodies that selectively recognized three, four, or five of immunotypes L1, L3 and L7-L12, but not with the rest within the recited immunotypes was explained. Mr. Tritel was informed that the Quality Assurance Specialist, Dr. Bonnie Eyler, was consulted on the new matter issue and he was encouraged to contact her if needed. That the proposed claim 60 still does not further limit claim 55 was indicated. Mr. Tritel was informed that Plested et al, 1999 would be retained as 102(b) art until the new matter rejection is overcome.

SD 02/28/06
S. DEVI, PH.D.
PRIMARY EXAMINER

 PEARL COHEN ZEDEK LATZER LLP

10 Rockefeller Plaza
Suite 1001
New York, NY 10020
USA
Tel 212.632.3480
Fax 212.632.3480

www.pczlaw.com

FACSIMILE

Direct Dial: 972-8-972-8026
Direct E-mail: MarcT@pczlaw.com

Date: February 27, 2006
To: Examiner Sarvamangala Devi, Art Unit 1645
Company: USPTO
From: Dr. Marc Tritel
App. No. 10/089,583
Our Ref.: P-6336-US (184537)
Subject: VACCINE
Fax No.: (274) 273-8300 571-273-0854
of Pages: 17

Message:

Dear Examiner Devi,

As we have discussed, I am faxing herewith a draft Amendment in response to the pending Office Action for the above-identified application. I look forward to speaking with you tomorrow, 9:00, to confirm that the Amendment overcomes all issues preventing allowance of this application.

Thank you very much.

Yours sincerely,



Dr. Marc Tritel
Pearl Cohen Zedek Latzer, LLP

cc: Mark S. Cohen

Expedited Procedure under 37 CFR 1.116
Group Art Unit (1645)

Attorney Docket No.: P-6336-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): PLESTED, Joyce S. et al. Examiner: DEVI, Sarvamangala J N
Serial No.: 10/089,583
Filed: July 11, 2002
Title: VACCINE

DRAFT AMENDMENT

Mail Stop AF
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amendment is filed in response to the Office Action dated November 2, 2005 issued by the United States Patent and Trademark Office in connection with the above-identified Application. A response to the November 2, 2005 Office Action was due February 2, 2006. Applicants are concurrently filing a Petition for a One-Month Extension of Time, including the required fee. Therefore, a response is due March 2, 2006. Accordingly, this Amendment is being timely filed.

Kindly amend the above-identified application as follows:

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AMENDMENTS TO THE CLAIMS

Please add or amend the claims to read as follows, and cancel without prejudice or disclaimer to resubmission in a divisional or continuation application claims indicated as cancelled:

1-47. Canceled.

48. (Currently Amended) A method for eliciting in a host an antibody that recognizes a plurality of *Neisseria meningitidis* immunotypes, said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12, comprising administering to said host an immunogenic composition, said immunogenic composition comprising an inner core of a *Neisseria* lipopolysaccharide (LPS), wherein a phosphoethanolamine moiety is linked to position 3 of a HepII moiety of said inner core of said [[a]] *Neisseria* LPS.

49. (Previously Presented) The method of claim 48, wherein said immunogenic composition does not comprise an outer core of said *Neisseria* LPS.

50. (Currently Amended) The method of claim 48, wherein said plurality of *Neisseria meningitidis* immunotypes comprises three or more of said *Neisseria meningitidis* immunotypes.

51. (Currently Amended) The method of claim 48, wherein said plurality of *Neisseria meningitidis* immunotypes comprises four or more of said *Neisseria meningitidis* immunotypes.

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52. (Currently Amended) The method of claim 48, wherein said plurality of *Neisseria meningitidis* immunotypes comprises five or more of said *Neisseria meningitidis* immunotypes.
53. (Currently Amended) The method of claim 52, wherein said plurality of *Neisseria meningitidis* immunotypes comprises all of said *Neisseria meningitidis* immunotypes.
54. Cancelled.
55. (Currently Amended) A method of immunizing a host against each of a plurality of *Neisseria meningitidis* immunotypes, said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12, comprising administering to said host an immunogenic composition, said immunogenic composition comprising an inner core of a *Neisseria* lipopolysaccharide (LPS), wherein a phosphoethanolamine moiety is linked to position 3 of a HepII moiety of said inner core of [[a]] said *Neisseria* LPS.
56. (Previously Presented) The method of claim 55, wherein said immunogenic composition does not comprise an outer core of said *Neisseria* LPS.
57. (Currently Amended) The method of claim 55, wherein said plurality of *Neisseria meningitidis* immunotypes comprises three or more of said *Neisseria meningitidis* immunotypes.

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58. (Currently Amended) The method of claim 55, wherein said plurality of *Neisseria meningitidis* immunotypes comprises four or more of said *Neisseria meningitidis* immunotypes.

59. (Currently Amended) The method of claim 55, wherein said plurality of *Neisseria meningitidis* immunotypes comprises five or more of said *Neisseria meningitidis* immunotypes.

60. (Currently Amended) The method of claim 59, wherein said plurality of *Neisseria meningitidis* immunotypes comprises all of said *Neisseria meningitidis* immunotypes.

61. Canceled.

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REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Status of Claims

Claims 48-53 and 55-60 are pending in the application. Claims 48-53 and 55-60 have been rejected. Claims 48, 50-53, 55, and 57-60 have herein been amended.

CLAIM REJECTIONS

35 U.S.C. § 112, First Paragraph Rejections

In the Office Action, the Examiner rejected claims 48-53 and 55-60 under 35 U.S.C. § 112, first paragraph, as allegedly containing new subject matter that was not sufficiently described in the specification. The Examiner alleged that the limitations "a plurality of *Neisseria meningitidis* immunotypes" and "said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12" lack descriptive support in the subject application as filed, because the application allegedly fails to show that an immunogenic composition comprising an inner core of any meningococcal or non-meningococcal *Neisseria* LPS, wherein a PEtN moiety is linked to position 3 of the HepII moiety, elicits an antibody against the *Neisseria meningitidis* (NM) immunotypes L1, L3, L7, L8, L9, L10, L11, and L12.

The Examiner further alleged that the description in the subject specification is limited to a method of eliciting a monoclonal antibody, MA b B5, by administering an immunogenic composition comprising formalin-killed whole cells of a galE NM mutant. The Examiner admitted, however, that the elicited antibody recognized NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12.

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In response, Applicants agree with the Examiner's admission that the elicited antibody recognized the named immunotypes, but respectfully disagree with the rejection.

Contrary to the Examiner's assertions, the disclosure of the subject specification is not limited to elicitation of MAb B5. MAb B5 was used in the experiments presented in the subject application merely as a tool to define the conserved epitope of the present invention. Accordingly, elicitation of MAb B5 is not an integral part of the methods demonstrated in the subject specification; rather, the subject specification shows that any antibody elicited by the conserved epitope will recognize other all *Neisseria* strains containing the conserved epitope, as will be demonstrated.

To support the above point, the subject specification unequivocally shows that:

- a. Antibody B5 recognized all tested *Neisseria* strains containing PEtN at this position, but not those strains lacking PEtN at this position, as admitted by the Examiner.
- b. Three collections of meningococcal strains – 153 distinct strains with geographically diverse origins, spanning a period of more than 40 years, representing disease isolates and all LPS immunotypes – were tested for B5 reactivity. The epitope was present in over 70% of strains and in all LPS immunotypes with PEtN on the 3 position of the Hcp2 (L1, L3, L7, L8, L9, L10, L11, or L12), while other immunotypes did not (p. 31-33 and Table 1 of the subject specification). The experiments were not limited to *Neisseria meningitidis*, but rather utilized several other *Neisseria* species. These findings provide irrefutable evidence of the requirement for PEtN on the 3 position of the Hcp2 as a necessary condition for B5 binding. Clearly, B5 reactivity defines an epitope that is present and accessible in a wide variety of meningococcal and non-meningococcal *Neisseria* strains, both capsule-deficient and fully encapsulated. Accessibility of the epitope was further confirmed by immunofluorescence studies (pages 51 and 58-59).
- c. To further support the above points, the subject application discloses the structural analysis of the conserved epitope using LPS mutants (page 29), silver stained gels (page 32 and Figure 6), ELISA (page 29), electrospray ionization mass spectrometry (pages 24 and 29), and molecular modeling (page 52).

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Thus, the preponderance of evidence presented in the subject application shows that the presence of a PEtN moiety linked to position 3 of HepII of a *Neisseria* inner core LPS defines an epitope that is (a) present and conserved; and (b) accessible on all *Neisseria* strains containing PEtN at position 3 of HepII.

The subject application also shows that:

- d. Antibodies elicited by the recited epitope were opsonic and bactericidal and passively protected subjects against *Neisseria meningitidis* infection (pages 56-58).
- e. NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12 contain PEtN linked to position 3 of HepII. (page 31, second full paragraph)

At the time of filing of the subject application, vaccine immunologists at the time of filing of the subject application had widely accepted the principles that (a) if a conserved, accessible epitope is present on an immunogenic composition, the composition will elicit antibodies against pathogens containing the conserved epitope; and (b) elicitation of protective antibodies by the epitope shows that administration of the immunogenic composition will protect against the pathogens containing the conserved epitope. These principles were so well accepted in the field that reactivity with protective antibodies against conserved epitopes was used as the criterion to identify synthetic mimetic peptides useful in vaccination, even though the mimetic peptides had no other resemblance to the pathogenic organism. For example, the Chargelegue reference, attached hereto, which was published in March 1998, before the filing date of the subject application, used reactivity with the protective monoclonal antibody MAb 19 to screen the peptide library:

"In the work described in this paper, a solid-phase combinatorial peptide library was used to identify peptides that mimic the epitope recognized by this neutralizing and protective MAb. When used as an immunogen, one of these mimotopes induced virus-neutralizing antibody responses and reduced viral load following challenge of mice with RSV" (paragraph

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beginning on page 2043; emphasis added; also see first paragraph of Materials and Methods section, p. 2041, and in caption to Table 1, p. 2042)

"It is important to note that the sequences identified by this type of approach do not necessarily have any similarity to the primary amino acid sequence of the F protein of RSV, but they mimic the conformation of the epitope" (paragraph beginning on page 2044; emphasis added).

In summary, a person skilled in the art would have accepted that the subject application credibly taught the existence of an epitope that is (a) defined by a PEtN moiety linked to position 3 of HepII of the inner core LPS, (b) conserved, (c) accessible, and (d) able to elicit antibodies, and further credibly taught that the conserved epitope is present on NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12. Thus, a person skilled in the art would have known that the presence of the conserved epitope recited in the subject claims in an immunogenic composition would be sufficient to elicit antibodies that recognize the *N. meningitidis* immunotypes recited in the subject claims. Accordingly, a person of average skill in the art would have reasonable expectation, based on the subject specification, that any *Neisseria* strain having a PEtN moiety linked to position 3 of HepII of the inner core LPS can be used to elicit antibodies that recognize NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, as recited in the subject claim.

Thus, the methods recited in the subject claims are sufficiently described and enabled by the subject specification.

Moreover, the Examiner has admitted that the above line of reasoning was accepted by those skilled in the art at the time of filing of the subject application, as evidenced by the Examiner's rejection of the subject claims under 35 U.S.C. § 102 as allegedly anticipated by the Plested et al reference (section 13, pages 6-7 of the Office Action; described in more detail below in the section traversing the rejection). Specifically, the Examiner alleged that, based on the demonstration by Plested that a conserved, accessible epitope is present both on the prior art composition and on *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11,

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and L12, the prior art composition would have been expected by a person skilled in the art to elicit antibodies that recognized these *N. meningitidis* immunotypes. Thus, *the Examiner admitted that those skilled in the art knew at the time of filing of the subject application that, if a conserved, accessible epitope is present on an immunogenic composition, the composition will elicit antibodies against pathogens containing the conserved epitope.* Accordingly, based on the Examiner's own admissions about what was known in the art, a person skilled in the art would have known that the presence of the conserved epitope recited in the subject claims in an immunogenic composition would be sufficient to elicit antibodies that recognize the *N. meningitidis* immunotypes recited in the subject claims.

Further, since a reference must be enabling to be used for anticipation under 35 U.S.C. § 102, as stated in the MPEP, Section 2121.01, the use of Plested by the Examiner in a U.S.C. § 102 rejection shows that the Examiner clearly believes that Plested would have *enabled* one skilled in the art *to practice the subject matter of the pending claims. All the data and description found in Plested are also found in the subject specification. Thus, the Examiner has in effect admitted that the subject specification enables the subject matter of the pending claims.*

Applicants therefore respectfully request that the rejection be withdrawn.

In addition, in order to clarify the record, Applicants disagree with the Examiner's characterization of the alleged limitations "a plurality of *Neisseria meningitidis* immunotypes" and "said *Neisseria meningitidis* immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12." The Examiner construed these limitations to require that all the named *Neisseria meningitidis* immunotypes be recognized by the elicited antibody.

Applicants respectfully disagree. The first definition of "plurality" in the Merriam-Webster Dictionary is "the state of being plural." Thus, the meaning of the limitation "a plurality of *Neisseria* immunotypes" is "more than one *Neisseria* immunotype." Any number equaling 2 or greater satisfies this limitation. Thus, the Examiner has misconstrued the above alleged limitations.

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Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that the limitations "three or more," "four or more," and "five or more" lack descriptive support in the application as filed, because the application allegedly does not show that an immunogenic composition comprising an inner core of any non-meningococcal *Neisseria* LPS, wherein a PEtN moiety is linked to position 3 of the HepII moiety, elicits an antibody against selectively just 3, 4, or 5, but not the rest of the named immunotypes. The Examiner admitted, however, that the lower limits of these alleged limitations are 3, 4, and 5, respectively.

In response, Applicants agree with the Examiner's admission that the lower limits of the above alleged limitations are 3, 4, and 5, respectively, but respectfully disagree with the rejection. The plain language of the phrases "three or more," "four or more," and "five or more" contradicts the Examiner's assertion that the elicited antibody must recognize selectively just 3, 4, or 5 of the named immunotypes. "Three" or "more," for example, means that either 3 or more of the named immunotypes may be recognized by the elicited antibodies. Thus, the Examiner has misconstrued the above alleged limitations.

Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that the phrase "a *Neisseria* LPS" recited in the last line of claims 48 and 55 is different from "said *Neisseria* LPS" recited in lines 5 and 6 of these claims.

In response, in order to expedite prosecution, Applicants have amended claims 48 and 55 to correct the typographical error.

Applicants therefore respectfully request that the rejection be withdrawn.

35 U.S.C. § 112, Second Paragraph Rejections

Further, the Examiner rejected claims 48-53 and 55-60 under 35 U.S.C. § 112, second paragraph, as allegedly failing to particularly point out and distinctly claim the subject matter

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regarded as the invention. The Examiner alleged that the limitation "said inner core of a *Neisseria* LPS" in claims 48 and 55 appears to lack proper antecedent basis

In response, in order to expedite prosecution, Applicants have corrected the typographical error in claims 48 and 55. Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that the limitation "said plurality of *Neisseria* immunotypes" near the beginning of claims 50, 51, 52, 52, 57, 58, 50, and 60 appears to lack proper antecedent basis, and is inconsistent with the phrase "said *Neisseria meningitidis* immunotypes" near the end of the claims.

In response, in order to expedite prosecution, amended claims 50, 51, 52, 52, 57, 58, 50, and 60 contain the phrase "said plurality of *Neisseria meningitidis* immunotypes" both near the beginning and near the end of the claims. Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that claims 57, 58, and 59 are confusing in scope, because they contain the alleged limitations "wherein said plurality of *Neisseria* immunotypes comprises...or more of said *Neisseria meningitidis* immunotypes."

In response, in order to expedite prosecution, amended claims 57, 58, and 59 contain the phrase "wherein said plurality of *Neisseria meningitidis* immunotypes comprises...or more of said *Neisseria meningitidis* immunotypes." Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner alleged that claims 55 and 60 are confusing with regard to their scope, because claim 60 contains the limitations "said plurality of... immunotypes comprises all of said...immunotypes." Thus, it is unclear to the Examiner how claim 60 further limits claim 60, which includes the alleged limitation "each of a plurality of...immunotypes, said...immunotypes selected from the group consisting of L1, L3, L7, L8, L9, L10, L11, and L12."

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Applicants respectfully disagree. As described above in the discussion of the 35 U.S.C. § 112, first paragraph rejections, the Examiner has misconstrued the meaning of the above limitation to require that all the named immunotypes be recognized by the elicited antibody. Rather, the correct interpretation is that two or more of the named immunotypes be recognized. Thus, the rejection is improper. Applicants therefore respectfully request that the rejection be withdrawn.

Further, the Examiner rejected claims 49-53 and 56-60 because of the alleged indefiniteness in the respective independent claims.

In response, in view of the traversal of the other rejections under 35 U.S.C. § 112, second paragraph, Applicants respectfully request that the rejection be withdrawn.

Applicants respectfully assert that these amendments render claims 48-53 and 55-60 proper under 35 U.S.C. 112 and request that the rejections be withdrawn.

35 U.S.C. § 102 Rejection

Further, the Examiner rejected claims 48-53 and 55-60 under 35 U.S.C. § 102(b), as being anticipated by the Plested et al reference (Infect Immun. 1999 Oct; 67(10): 5417-26). The Examiner alleged (section 13, pages 6-7 of the Office Action) that Plested taught (a) a method of eliciting B5 monoclonal antibody that is specific to LPS inner core, comprising administering to mice an immunogenic composition comprising formalin-killed whole cells of a group B *N. meningitidis* L3 immunotype that comprises the LPS inner core; (b) that the inner core LPS contains an epitope recognized by the monoclonal antibody, B5 and is characterized by the presence of a PEtN moiety linked to the 3' position at HepII of the inner core.; (c) that the inner core LPS in the composition consists of an inner core LPS attached to lipid A and has the formula depicted in Figure 1a of the subject specification; (d) that B5 specifically recognized *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12; (e) and that B5 is opsonic. In summary, the Examiner alleged that, based on the demonstration by Plested that a conserved, accessible epitope is present both on the prior art composition and on *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, the

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prior art composition would have been expected by a person skilled in the art to elicit antibodies that recognized these *N. meningitidis* immunotypes.

Further, the Examiner refused to grant priority to the subject claims from U.S. Provisional Applications 60/196,305, filed 4/12/00, and 60/156,940, filed 09/30/99, alleging that the subject claims lack descriptive support in Provisional Applications 60/196,305 and 60/156,940. Thus, Plested was used as a prior art reference under 35 U.S.C. § 102(b).

Applicants respectfully disagree, and assert that the amended claims are adequately supported and described in U.S. Provisional Application 60/156,940, which shows, using the same data, that:

- a. Antibody B5 recognized all tested *Neisseria* strains containing PEtN at this position, but not those strains lacking PEtN at this position, as admitted by the Examiner (page 16, lines 7-9 of U.S. Provisional Application 60/156,940).
- b. B5 reactivity defines an epitope that is present, conserved and accessible in a wide variety of meningococcal and non-meningococcal *Neisseria* strains (lines 1-3 of the first full paragraph on page 18 of U.S. Provisional Application 60/156,940).
- c. To further support the above points, U.S. Provisional Application 60/156,940 discloses the structural analysis of the conserved epitope using LPS mutants (page 13), silver stained gels (page 17 and Figure 6), ELISA (page 14), electrospray ionization mass spectrometry (pages 7 and 13), and molecular modeling (p. 52).

As described above in the discussion of the 35 U.S.C. § 112, first paragraph rejections, vaccine immunologists at the time of filing of the subject application had widely accepted the principles that (a) if a conserved, accessible epitope is present on an immunogenic composition, the composition will elicit antibodies against pathogens containing the conserved epitope; and (b) elicitation of protective antibodies by the epitope shows that administration of the immunogenic composition will protect against the pathogens containing the conserved epitope. Accordingly, a person of average skill in the art would have reasonable expectation, based on U.S. Provisional Application 60/156,940, that any *Neisseria*

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strain having a PEtN moiety linked to position 3 of HepII of the inner core LPS can be used to elicit antibodies that recognize NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12.

In addition, U.S. Provisional Application 60/196,305 further elaborates upon the findings of Provisional Application 60/156,940.

Thus, the methods recited in the subject claims were sufficiently described and enabled by U.S. Provisional Application 60/156,940 and U.S. Provisional Application 60/196,305.

Moreover, the Examiner's allegations are self-contradictory. The Examiner has alleged that, based on the demonstration by Plested that a conserved, accessible epitope is present both on the prior art composition and on *N. meningitidis* immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, the prior art composition would have been expected by a person skilled in the art to elicit antibodies that recognized these *N. meningitidis* immunotypes. Thus, the Examiner admitted that those skilled in the art knew at the time of filing of the subject application that, if a conserved, accessible epitope is present on an immunogenic composition, the composition will elicit antibodies against pathogens containing the conserved epitope. As described above, U.S. Provisional Application 60/156,940 credibly taught the existence of an epitope that is (a) defined by a PEtN moiety linked to position 3 of HepII of the inner core LPS, (b) conserved, (c) accessible, and (d) able to elicit antibodies, and further credibly taught that the conserved epitope is present on NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12. Accordingly, based on the Examiner's own admissions about what was known in the art, a person skilled in the art would have known that the presence of the conserved epitope recited in the subject claims in an immunogenic composition would be sufficient to elicit antibodies that recognize the *N. meningitidis* immunotypes recited in the subject claims. Consequently, a person of average skill in the art would have reasonable expectation, based on U.S. Provisional Application 60/156,940, that any *Neisseria* strain having a PEtN moiety linked to position 3 of HepII of the inner core LPS can be used to elicit antibodies that recognize NM immunotypes L1, L3, L7, L8, L9, L10, L11, and L12, as recited in the subject claims.

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Thus, the methods recited in the subject claims were sufficiently described and enabled by U.S. Provisional Application 60/156,940 and U.S. Provisional Application 60/196,305.

Further, since a reference must be enabling to be used for anticipation under 35 U.S.C. § 102, as stated in the MPEP, Section 2121.01, the use of Plested by the Examiner in a U.S.C. § 102 rejection shows that the Examiner clearly believes that Plested would have *enabled* one skilled in the art *to practice the subject matter of the pending claims*. Plested contains the *same data* as Provisional Application 60/156,940. Thus, the Examiner *has in effect admitted that Provisional Application 60/156,940 enables the subject matter of the pending claims*.

Since the new claims are supported by U.S. Provisional Applications 60/196,305 and 60/156,940, Applicants respectfully request that the Examiner grant claims of the subject application a priority of U.S. Provisional Applications 60/196,305 and 60/156,940, and consequently, withdraw the rejection under 35 U.S.C. § 102(b).

In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.

Respectfully submitted,
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Mark S. Cohen

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Attorney/Agent for Applicant(s)
Registration No. 42,425

Dated: February 27, 2006

Pearl Cohen Zedek Latzer, LLP
10 Rockefeller Plaza, Suite 1001
New York, New York 10020
Tel: (212) 632-3480
Fax: (212) 632-3489

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